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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,476	02/08/2002	Young-Jin Chae	10933-017	8647
20583	7590	12/28/2004		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017				
			EXAMINER KATCHEVES, KONSTANTINA T	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,476

Applicant(s)

CHAE, YOUNG-JIN

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 5 is/are allowed.
- 6) ☒ Claim(s) 1 and 6-8 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8 are pending in the present application.

Response to Amendment

The rejection of claims 1, 4 and 6 under 35 U.S.C. 102(b) as being anticipated by Hawley-Nelson et al. (US Patent No. 5,736,392) is withdrawn in view of Applicant's amendment.

The rejection of claims 1-4 and 6-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicant's amendments.

The rejection of claims 4 and 5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-8 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* methods for expression, does not reasonably provide enablement for *in vivo* methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Response to Arguments

Claims 6-8 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* methods for expression, does not reasonably provide

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enablement for *in vivo* methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues that the uncertainty in the art relative to methods of gene delivery to target cells *in vivo* are related to “older” means of *in vivo* gene transfer. Applicant states that such difficulties are “inherent in the use of viral vectors, wherein one must consider the toxicity of the virus, placement of the transgene into the appropriate segment or portion of the host virus genome, efficiency of packaging, non-transfection of certain cell types, communicability. . .” See Remarks, page 11. The problems discussed by the examiner are generally applicable to the present method, in addition to other modes of delivery, whether or not the method is drawn to viral vectors, as argued by Applicant. First, Verma et al. states at the outset that one of the primary problems is getting “enough of the DNA into these [target] cells.” See Verma, page 239, first paragraph. This problem is universal and would not change whether the vector is viral, liposomal, naked DNA or the protein-DNA complex claimed. The question remains whether one gets enough DNA into the intended cells. Verma states:

The Achilles heel of gene therapy is gene delivery Thus far, the problem has been an inability to delivery genes efficiently and to obtain sustained expression. There are two categories of delivery vehicle (‘vector’). The first comprises the non-viral vectors, ranging from injection of DNA to mixing the DNA with polylysine or cationic lipids that allow the gene to cross the cell membrane. Most of these approaches suffer from poor efficiency of delivery and transient expression of the transgene.... transient expression of the transgene is a conceptual hurdle that needs to be addressed. See Verma, column 3.

Here, Verma discusses a substantial hurdle that must be overcome to enable gene therapy methods and discloses that this hurdle is an obstacle to non-viral delivery methods such as the one claimed by Applicant. Therefore, contrary to Applicant’s position, Verma and the obstacles

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to gene therapy generally taught by each of the cited references is applicable to non-viral and viral methods of gene delivery.

Applicant's disclosure has failed to overcome the hurdle discussed in detail by the cited references. Applicant refers to examples 1-3 and lines 19-20 of page 11, as a working example that sufficiently enables the claimed method. Although Applicant cites an example wherein mRNA levels of GFP is measured using GFP specific primers, this example fails to provide enablement for at least three reasons. First, it does not overcome the problem of gene delivery to targeted cells. Second, it does not solve the problem of transient expression. Finally, it fails to show that the transferred protein was translated so that the desired protein would be expressed at sufficiently levels to produce a desired function in the target cells. Thus, for the reasons set forth in the prior Office action and those set forth above, the claimed method does not enable one of skill in the art to make or use the invention commensurate with the scope of the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . .[emphasis added].” A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The instant claims are drawn to protein-DNA complex comprising a leader peptide, a linker DNA and a nucleic acid sequence of interest. These are genus claims that encompass a wide array of molecules. The specification does not disclose a sufficient number of representative species of the genus to indicate that Applicant had possession of these claims. Moreover, the specification fails to provide any teachings as to how the structures of these sequences relate to their function. Thus, the specification does not describe the complete structure of a representative number of species. The specification also fails to describe a representative number of species in terms of partial structure and relevant identifying characteristics. Absent such teachings and guidance as to the structure-function relationship of these molecules, the specification does not describe the claimed protein-DNA complexes in such

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full, clear, concise and exact terms so as to indicate that Applicant had possession of this broad genus at the time of filing of the present application.

Allowable Subject Matter

Claims 2-5 are free of the prior art.

Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Examiner
Art Unit 1636



JAMES KETTER
PRIMARY EXAMINER